

## **REMARKS**

### **I. The Claims**

Claims 1, 3, 24 and 31-48 are pending and presently under examination.

Claims 1, 24 and 31-37 have been amended herein. Support for the amendment of claim 1 is found, for example, at page 11, l. 3-8. Support for the amendment of claim 24 is found in base claim 1.

Claims 31-37 have been amended to more clearly recite the claimed invention by eliminating disagreement between the singular form “antibody” recited in base claim 1 and the plural “antibodies” previously recited in claims 31-37. Support for the amendment of claims 31-37 is found in originally filed claim 1.

No new matter has been added by any of the amendments made herein.

### **II. Claim rejections under 35 U.S.C. §112, first paragraph, Written Description**

Claims 1, 3, 24 and 31-48 were rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description. (Office Action, ¶6 – page 4, l. 19 to page 8, l. 4.) Specifically, the Examiner asserted that the written description is inadequate because the present claims recite an antibody fragment “that comprises a hypervariable region” and that binds to EGFR, but the “hypervariable region” is allegedly not a term of art and even if the term is reasonably interpreted to mean “CDR,” the claims nevertheless lack adequate written description since their present language would include antibody fragments that bind EGFR but which have only a *single* CDR and it is allegedly known that a single CDR alone cannot impart specific binding. (Office Action, page 5, l. 3 to page 6, l. 13 and entire section.)

The present rejection is overcome for the following reasons.

Independent claim 1 has been amended herein to recite that the claimed antibody or antibody fragment specifically binds EGFR and to eliminate the prior recitation of “hypervariable region” which the Examiner objected to as not being a term of art and as

improperly putting within the scope of the claim an antibody fragment containing only a single CDR.

As set forth in Example 16 (page 59) of the Office's Synopsis of Written Description Guidelines, "[t]he general knowledge in the art is such that antibodies are structurally well characterized;" "[a]ntibodies contain an effector region that is the constant region and variable region that contains the antigen binding sites in the form of complementarity determining regions and framework regions;" and "[i]t is also well known that antibodies can be made against virtually any protein." Accordingly, Applicants submit that, as a result of the amendment of claim 1 herein and the art-recognized maturity of antibody technology, the presently amended claims are in compliance with the written description requirement.

In view of the above, withdrawal of the present claim rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

### **III. Claim rejections under Doctrine of Obviousness-Type Double Patenting**

Claims 1, 3, 24 and 31-48 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-10 of copending U.S. application serial no. 11/206,825 ("the copending application"): (Office Action, page 8, l. 5 to page 9, l. 6.) Specifically, the Examiner has alleged double patenting on the asserted basis that claims 1-10 of the copending application "are drawn to methods of inhibiting tumor growth comprising administering antibodies that bind EGFR, at least one chemotherapeutic agent and radiation therapy" and "[t]hus these claims are a species of the claims of the instant application." (Office Action, page 8, l. 29 to page 9, l. 2.)

The present rejection of the claims is overcome for the following reasons.

Cited U.S. application serial no. 11/206,825 is not co-owned with Applicants' instant application and does not have the same inventorship as Applicants' instant application – only inventor Buchsbaum is common between the two applications. Accordingly, the rendered rejection for obviousness-type double patenting is not applicable.

Further, with respect to obviousness under 35 U.S.C. §103(a), Applicants wish to point out that the earliest effective filing date of the instant application, i.e. May 15, 1998, is earlier than the earliest claimed priority in cited U.S. application serial no. 11/206,825, which is December 8, 2000. The present application is also a divisional of U.S. application serial no. 09/312,286 filed May 14, 1999. Accordingly, the application cited by the Examiner is not available as a prior art reference against the instant application.

In view of the above, Applicant respectfully requests withdrawal of the present rejection of the claims for obviousness-type double patenting.

#### **IV. Conclusion**

Pursuant to this paper, Applicants submit that pending claims 1, 3, 24 and 31-48 are in condition for further examination and allowance, which action is hereby requested.

No fees other than those mentioned above should be due in connection with the filing of this paper. However, if any additional fees are found to be required, the Office is hereby authorized to charge any and all such fees to Deposit Account No. 02-2275.

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Respectfully submitted,

  
LUCAS & MERCANTI, LLP

Michael N. Mercanti  
Reg. No. 33,966

LUCAS & MERCANTI, LLP  
475 Park Avenue South  
New York, New York 10016  
Phone: 212-661-8000  
Fax: 212-661-8002

Customer No. 20311

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LUCAS & MERCANTI, LLP

BY: 

Michael N. Mercanti